

1083764

## 510(k) Summary: Amphetamines II Assay, Hitachi 917

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**Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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**Submitter  
Name, Address,  
Contact** Roche Diagnostics  
9115 Hague Rd.  
Indianapolis, IN 46250  
317-521-3742

FEB - 3 2010

Contact Person: Michelle Neff

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**Device Name** Proprietary name: Amphetamines II

Common name: Amphetamine metabolite test system

Classification name:

Enzyme Immunoassay, Amphetamine  
Gas Chromatography, Methamphetamine

Product Code: DKZ, LAF

**Device  
Description**

The Amphetamines II assay is based on the kinetic interaction of microparticles in a solution (KIMS) as measured by changes in light transmission. In the absence of sample drug, soluble drug-polymer conjugates bind to antibody-bound microparticles, causing the formation of particle aggregates. As the aggregation reaction proceeds in the absence of sample, the absorbance increases.

When a urine sample contains the drug in question, this drug competes with the conjugate-bound drug derivative for microparticle-bound antibody. Antibody bound to sample drug is no longer available to promote particle aggregation, and subsequent particle lattice formation is inhibited.

The presence of sample drug diminishes the increasing absorbance in proportion to the concentration of drug in the sample. Sample drug content is determined relative to the value obtained for a known cutoff concentration of drug.

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### Intended Use

Amphetamines II (AMPII) is an in vitro diagnostic test for the qualitative and semiquantitative detection of amphetamines and methamphetamines on automated clinical chemistry analyzers at cutoff concentrations of 300 ng/mL, 500 ng/mL and 1000 ng/mL when calibrated with *d*-methamphetamine. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program. Semiquantitative assays are intended to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as gas chromatography/mass spectrometry (GC/MS).

**Amphetamines II provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.<sup>1</sup> Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.**

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### Comparison to the Predicate Device

The ONLINE Amphetamines II assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, we claim substantial equivalence to the currently marketed Abuscreen ONLINE Amphetamines assay (K983699).

The ONLINE Amphetamines II assay contains an in vitro diagnostic reagent system intended for use on the Roche/Hitachi 917 analyzer for the semi-quantitative and qualitative detection of amphetamines in human urine at cutoff concentrations of 300, 500, and 1000 ng/mL.

The Roche ONLINE Amphetamines II assay utilizes a modified KIMS technology relative to the currently marketed Abuscreen OnLine Amphetamines assay. Differences between this application and the cleared assay include:

1. use of amphetamine and methamphetamine, and monoclonal antibodies attached to microparticles in solution
2. a soluble drug-polymer conjugate
3. increased sensitivity to "designer drugs" and their metabolites, and
4. addition of 300 and 500 ng/mL cutoff concentrations.

The recommended calibrators to be used with the proposed ONLINE Amphetamines II assay are the Preciset DAT Plus I, Preciset DAT Plus II and Cfas DAT Qualitative Plus Calibrators (K060645).

The recommended controls to be used with the proposed ONLINE Amphetamines II assay are the Control Set DAT I, Control Set DAT II, Control Set DAT III (K080183).

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Feature	Roche Amphetamines II Assay	Predicate Device: ONLINE Amphetamines (K983699)
Methodology	Same	KIMS, Kinetic interaction of microparticles in solution
Sample Type	Same	Urine
Intended Use	Qualitative and semi-quantitative detection of amphetamine and methamphetamine	Qualitative and semi-quantitative detection of amphetamine and methamphetamine and their metabolites
Cutoff	300, 500, 1000 ng/mL	1000 ng/mL
Calibrator/Control Matrix	Same	Human urine

## 510(k) Summary: Amphetamines II Assay, Hitachi 917

Feature	Roche Amphetamines II Assay	Predicate Device: Abbott Amphetamine/Methamphetamine (K012998)
Methodology	KIMS, Kinetic interaction of microparticles in solution	Homogenous enzyme immunoassay
Sample Type	Same	Urine
Intended Use	Qualitative and semi-quantitative detection of amphetamine and methamphetamine	Qualitative detection of amphetamine/methamphetamine
Cutoff	300, 500, 1000 ng/mL	1000 ng/mL
Calibrator/Control Matrix	Same	Human urine



## DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center – WO66-0609  
Silver Spring, MD 20993-0002

Roche Diagnostics Corporation  
c/o Ms. Michelle Neff  
Regulatory Principal  
9115 Hague Road  
Indianapolis, IN 46250

FEB - 3 2010

Re: k083764  
Trade Name: ONLINE DAT II Amphetamines II  
Regulation Number: 21 CFR §862.3100  
Regulation Name: Enzyme Immunoassay, Amphetamine  
Regulatory Class: Class II  
Product Codes: DKZ, LAF  
Dated: December 02, 2009  
Received: December 03, 2009

Dear Ms. Neff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

Courtney C. Harper, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known):

Device Name: **ONLINE DAT II Amphetamines II**

Indication For Use:

Amphetamines II (AMPII) is an in vitro diagnostic test for the qualitative and semiquantitative detection of amphetamines and methamphetamines on automated clinical chemistry analyzers at cutoff concentrations of 300 ng/mL, 500 ng/mL and 1000 ng/mL when calibrated with *d*-methamphetamine. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program. Semiquantitative assays are intended to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as gas chromatography/mass spectrometry (GC/MS).

**Amphetamines II provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.<sup>1</sup> Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.**

Prescription Use XXX  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use \_\_\_\_  
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K083764